REMARKS

I. The Office Action

The July 27, 2006 final office action (the "Office Action") in this application rejected claims 35, 37-39, 42-47, 51-52, 55-56, 61-67 and 82-92 under 35 U.S.C. 103(a) as being unpatentable over Wong (U.S. patent 5,869,079).

Applicants responds to the Office Action as follows.

II. Request for Continued Examination

This response to the Office Action is filed with a request for continued examination ("RCE") after receipt by applicants of a final office action and with payment of the required fee. Hence the RCE is appropriate and the examiner is asked to withdraw the finality of the Office Action and enter this response.

III. Prosecution History of this Application

The prosecution history of this application can be summarized as follows:

1. the parent application serial number 09/693,008 issued as U.S. patent 6,726,918 on April 27, 2004.

2. the present application serial number 10/671, 816 is a continuation patent application filed September 25, 2003.

3. a preliminary amendment in this application was filed April 1, 2004 cancelling the original claims and adding new claims.

4. a first non-final office action was issued by examiner Casey Rosenthal on January 11, 2005 rejecting the claims under section 112(1), and under section 103(a) as being unpatentable over the Wong '079 patent, and over the combination of Wong '079 and Guo.

5. a response to the January 11, 2005 office action was filed by applicants on April 13, 2005.

6. a final office action was issued by examiner Casey Hagopian on July 11, 2005 withdrawing the section 112(1) rejection, but again rejecting the claims under section 103(as) as being unpatentable over the Wong '079 patent and over the combination of Wong '079 and Guo.

7. a request for continued examination (RCE) and a response to the July 11, 2005 final office action was filed by applicants on October 12, 2005.

8. a non-final office action was issued by examiner Casey Hagopian on January 12, 2006 rejecting claims under sections 112(1) and 112(2). There were no art rejections in the office action.

9. a response to the January 12, 2006 office action was filed by applicants on March 24, 2006.

10. a final office action (the present Office Action) was issued by examiner Pili Hawes on July 27, 2006 rejecting the claims under section 103(a) as being unpatentable over the Wong '079 patent. Page 2 of the office action states that "the rejections made in the previous office action 07-11-2005 are re-presented and maintained".

Thus, numbered paragraphs 6-8 on page 3-5 of the July 27, 2006 office action are identical (but for the numbering of the corresponding claims) to numbered paragraphs 6-8 on pages 3-4 of the July 11, 2005 office action.

Additionally, numbered paragraphs 9-10 on page 5-6 of the July 27, 2006 office action are identical to numbered paragraphs 11-12 on page 6 of the July 11, 2005 office action. The only difference with regard to these parts of these two office actions is that: the July 11, 2005 office action states (at the top of page 6) that "Applicant's arguments filed 4/13/2005 have been fully considered but they are not persuasive", while the corresponding part of the July 27, 2006 office action (middle of page 5) states ""Applicant's arguments filed 4/13/2005 and 03-24-2006 have been fully considered but they are not persuasive" (emphasis added).

Thus, as stated in the July 27, 2006 office action, this Office Action has not considered applicant's arguments filed October 12, 2005.

This is an important point because the July 27, 2006 office action has reapplied (word for word) the rejection over Wong made in the July 11, 2005 office action. But the fact is that applicants responded to the rejection over Wong in the July 11, 2005 office action in applicant's response filed October 12, 2005. Furthermore, the response filed by applicant's October 12, 2005 has already overcame the rejection made in the July 11, 2005 office action over Wong, because the next office action, which issued on January 12, 2006, had only sections 112(1) and 112(2) rejections - there was no art rejections in the January 12, 2006 office action.

For the convenience of the examiner applicants set forth below the arguments made by applicants in the response filed October 12, 2005, revised to reflect new claim numberings and the intervening claim amendments.

IV. The Section 103(a) Rejection Over Wong

The Office Action rejected claims 35, 37-39, 42-47, 51-52, 55-56, 61-67 and 82-92 under 35 U.S.C. section 103(a) as being unpatentable over Wong et al (U.S. patent 5,869,0790. Respectfully, the rejection is in error and should be withdrawn.

As stated by the Office Action, the Wong reference discloses a PLGA implant containing dexamethasone. The Office Action states in numbered paragraph 7 on pages 3-4 of the Office Action that since the instant claims are product claims an intended use does not provide a patentable distinction because "if a prior art structure (i.e. Wong) is capable of performing the intended use, then it meets the claim." (this statement is also repeated on pages 5-6 in numbered paragraph 10 of the Office Action). It is also noted by page 5, numbered paragraph 8 of the Office Action that while Wong does not teach the exact claimed formulations and rates of release, these claimed differences are obvious since Wong suggests changing the size and form of the implant and the Office Action cites to columns 7-8 of Wong for this point, noting that a person of ordinary skill would have been motivated to make such modification, to thereby arrive at the claimed invention.

In light of these comments in the Office Action applicants have amended the claims to limit the claims to an implant which clearly distinguishes over the implant disclosed by Wong. As explained below, the prior art structure of Wong is not capable of performing the intended use of the claimed subject matter, and therefore the amended claims are patentable over Wong.

The claims have been amended to add the following limitations to the claims:

1. "the implant being an extruded filament" (All Claims). This new claim limitation is supported by at least page 26, paragraph [0089] of Example 6 of the specification ("...filaments extruded...The resulting filaments...")

2. "the implant having a weight between about 500 µg and about 1100 µg" (claims 35, 37-39, 42-47,51-52, 55-56, 61-67). This new claim limitation is supported by at least page 18, paragraph [0062] of Example 1 of the specification ("...900-1100 µg..."), and by page 26, paragraph [0089] of Example 6 of the specification ("...500µg and 1000 µg...").

3. "the implant having a weight of about 250-5000 µg " (claims 82-92). This new claim limitation is supported by at least paragraph [0055] of the specification.

4. "the implant delivers at least about 20% of the agent within about 20 days in vitro". (Claims 35, 37-38, 42-47, 51 and 82-92). This new claim limitation is supported by at least: (1) Table 6 for replicate 1 on page 26 of the specification (note that by day 20 just over 30% of the agent had been released from the implant in vitro; (2) Table 6 for replicate 2 on page 27 of the specification (note that by day 20 almost exactly 20% of the agent had been released from the implant in vitro; (3) Table 7 for replicate 1 on page 28 of the specification (note that by day 20 over 23% of the agent had been released from the implant in vitro; (4) Table 7 for replicate 2 on page 28 of the specification (note that by day 20 just over 19% of the agent had been released from the implant in vitro.

5. "the implant delivers at least about 30% of the agent within about 20 days in vitro". (Claims 39, 52, 55-56 and 61-67). This new claim limitation is supported by at least Table 6 for replicate 1 on page 26 of the specification (note that by day 20 just over 30% of the agent had been released from the implant in vitro.

As noted by the last sentence of numbered paragraph 7 on page 4 of the Office Action: "Wong et al. also teach that the size and form of the implant can be used to control the rate of release, period of treatment , and drug concentration (column 7, lines 52-54)". Note that Wong then immediately states: "Larger implants will deliver a proportionately larger dose, but depending on the surface to mass ratio, may have a slower release rate."

6. All claims in the instant application are "consisting essentially of" format claims, which claim format is supported by at least paragraph [0056] of the specification. All claims therefore clearly exclude use of any release modifier.

It is important to note that only (the first part of) Example 1 of Wong sets forth an implant which does not include a release modifier. Furthermore, these no release modifier implants in Example 1 of Wong are small extruded filaments weighing only 100-120 µg.

Example 1 at column 8, lines 44-46 of Wong states that the drug released very slowly from the small extruded filaments. Thus, as shown by FIG 1A of Wong after 20 days in vitro only about 10% of the drug had been released.

An implant shaped as a sheet, film, circular disc or plaque (see column 7, lines 39-40 of Wong) has a high surface are to mass ratio, as compared to an implant which is shaped as a filament (i.e. a rod shaped implant). As easily understood, an implant will release more drug if it has a high surface to mass ratio, as compared to an implant which has a lower surface to mass ratio (other factors [such as the absence of a release modifier] being held constant).

Thus, Wong found that small (100 ug to 120 µg) filament shaped implants *which do not have a release modifier* release drug slowly (column 8, lines 44-48), and Wong states that although a larger implant can deliver more drug, it will have a slower release rate unless the surface to mass ratio is increased (i.e. change

the shape of the implant form a filament to a sheet or film shape) (column 7, lines 53-56 of Wong).

Clearly, therefore Wong does not teach or suggest that a larger implant with the same shape ("filament") made in the same way ("extruded") and which therefore has the same surface to mass ratio, will release drug faster than a smaller extruded filament implant. In fact, Wong clearly teaches away from the claims as amended, which are limited to an extruded filament implant which releases at least 20% of the drug after 20 days in vitro. Wong states or at least strongly implies that to get such a faster drug release with a larger implant one must either use an implant which has a higher surface area to mass ratio, as compared to a filament shaped implant, or (as done by Wong) use the same filament shaped implant but add one or more release modifiers (see Wong column 8, line 48, continuing to column 10.

Since the current claims have been amended to be limited to implants which (1) are substantially larger than the small implants of Wong which did not have release modifiers; (2) to exclude the presence of any release modifiers (the consisting essentially of claim format), and; (3) with a release profile which Wong teaches is not possible with a larger implant (i.e. larger than about 120 µg) unless a release modifier is present in the implant, therefore the claims as amended are distinguished over Wong and the rejection should be withdrawn.

V. Conclusion

All issues raised by the Office Action have been addressed. Examination and allowance of claims 35, 37-39, 42-47, 51-52, 55-56, 61-67 and 82-92 is requested.

Respectfully submitted,

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MARKED UP VERSION OF THE CLAIMS

1-34. (Cancelled)

35. (Currently amended) A bioerodible implant for treating an inflammation-mediated condition of an eye in an individual, the implant consisting essentially of ~~comprising~~ a steroidal anti-inflammatory agent and a bioerodible copolymer, the implant structured to be placed in the vitreous of the eye by being an extruded filament, the implant having a weight between about 500 µg and about 1100 µg and releasing at least about 20% of the agent within about 20 days in vitro.

36. (Cancelled)

37. (Previously amended) The bioerodible implant according to claim 35, wherein the steroidal anti-inflammatory agent is selected from the group consisting of cortisone, dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone, triamcinolone and mixtures thereof.

38. (Previously amended) The bioerodible implant according to claim 35, wherein the steroidal anti-inflammatory agent is dexamethasone.

39. (Previously amended) The bioerodible implant according to claim 35, wherein the implant releases at least about 30% of the agent after about 20 days in vivo.

40–41 (Canceled)

42. (Previously amended) The bioerodible implant according to claim 35, wherein the steroidal anti-inflammatory agent comprises about 50 to about 80 weight percent of the implant.

43. (Previously amended) The bioerodible implant according to claim 42, wherein the steroidal anti-inflammatory agent comprises about 70% by weight of the implant.

44. (Previously amended) The bioerodible implant according to claim 35, wherein the bioerodible copolymer is a polyester.

45. (Previously amended) The bioerodible implant according to claim 44, wherein the bioerodible copolymer is polylactic acid polyglycolic acid (PLGA) copolymer.

46. (Previously amended) The bioerodible implant according to claim 35, wherein the condition of the eye to be treated is selected from the group consisting of uveitis, macular edema, macular degeneration, retinal detachment, ocular tumors, fungal infections, viral infections, multifocal choroiditis, diabetic uveitis, proliferative vitreoretinopathy (PVR), sympathetic opthalmia, Vogt Koyanagi-Harada (VKH) syndrome, histoplasmosis, and uveal diffusion.

47. (Previously amended) The bioerodible implant according to claim 46, wherein the condition of the eye to be treated is uveitis.

48-50 (Canceled)

51. (Previously amended) The bioerodible implant according to claim 35, wherein the individual whose eye is to be treated is a human.

52. (Currently amended) An implant for treating an inflammation-mediated condition of the eye in an individual, the implant consisting essentially of ~~comprising~~ a solid body with ~~comprising~~ particles of a steroidal anti-inflammatory agent entrapped within a bioerodible copolymer, the body structured for

placement into the vitreous of the eye by being an extruded filament, the solid body having a weight between about 500 μg and about 1100 μg and releasing at least about 30% of the agent within about 20 days in vitro.

53-54 (Cancelled)

55. (Previously presented) The implant according to claim 52, wherein the steroidal anti-inflammatory agent is selected from the group consisting of cortisone, dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone, triamcinolone and mixtures thereof.

56. (Previously presented) The implant according to claim 52, wherein the steroidal anti-inflammatory agent is dexamethasone.

57-60 (Canceled)

61. (Previously presented) The implant according to claim 52, wherein the steroidal anti-inflammatory agent comprises about 50 to about 80 weight percent of the implant.

62. (Previously presented) The implant according to claim 61, wherein the steroidal anti-inflammatory agent comprises about 70% by weight of the implant.

63. (Previously presented) The implant according to claim 61, wherein the steroidal anti-inflammatory agent comprises about 50% by weight of the implant.

64. (Previously presented) The implant according to claim 52, wherein the bioerodible copolymer is a polyester.

65. (Previously presented) The implant of claim 52, wherein the bioerodible copolymer is polylactic acid polyglycolic acid (PLGA) copolymer.

66. (previously amended) The implant according to claim 52, wherein the inflammatory-mediated condition of the eye to be treated is selected from the group consisting of uveitis, macular edema, macular degeneration, retinal detachment, ocular tumors, fungal infections, viral infections, multifocal choroiditis, diabetic uveitis, proliferative vitreoretinopathy (PVR), sympathetic opthalmia, Vogt Koyanagi-Harada (VKH) syndrome, histoplasmosis, and uveal diffusion.

67. (Previously presented) The implant according to claim 66, wherein the inflammation-mediated condition of the eye to be treated is uveitis.

68-81 (Cancelled)

82. (Currently amended) A bioerodible implant for treating an inflammation-mediated condition of an eye in an individual, the implant consisting essentially of ~~comprising~~ a steroidal anti-inflammatory agent and a bioerodible copolymer, the implant structured to be placed in the vitreous of the eye by being an extruded filament, the implant having a weight of about 250-5000 µg and releasing at least about 20% of the agent within about 20 days in vitro.

83. (Previously presented) The bioerodible implant according to claim 82, wherein the steroidal anti-inflammatory agent is selected from the group consisting of cortisone, dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone, triamcinolone and mixtures thereof.

84. (Previously presented) The bioerodible implant according to claim 82, wherein the steroidal anti-inflammatory agent is dexamethasone.

85. (Previously presented) The bioerodible implant according to claim 82, wherein the implant releases at least about 30% of the agent after about 20 days in vivo.

86. (Previously presented) The bioerodible implant according to claim 82, wherein the steroidal anti-inflammatory agent comprises about 50 to about 80 weight percent of the implant.

87. (Previously presented) The bioerodible implant according to claim 86, wherein the steroidal anti-inflammatory agent comprises about 70% by weight of the implant.

88. (Previously presented) The bioerodible implant according to claim 82, wherein the bioerodible copolymer is a polyester.

89. (Previously presented) The bioerodible implant according to claim 88, wherein the bioerodible copolymer is polylactic acid polyglycolic acid (PLGA) copolymer.

90. (Previously presented) The bioerodible implant according to claim 82, wherein the inflammation-mediated condition of the eye to be treated is selected from the group consisting of uveitis, macular edema, macular degeneration, retinal detachment, ocular tumors, fungal infections, viral infections, multifocal choroiditis, diabetic uveitis, proliferative vitreoretinopathy (PVR), sympathetic opthalmia, Vogt Koyanagi-Harada (VKH) syndrome, histoplasmosis, and uveal diffusion.

91. (Previously presented) The bioerodible implant according to claim 90, wherein the inflammation-mediated condition of the eye to be treated is uveitis.

92. (Previously presented) The bioerodible implant according to claim 82, wherein the individual whose eye is to be treated is a human.